K020269

MAR 2 7 2002

VII. 510(k) SUMMARY

Manufacturer Information:

Submitters Name:	Procera Sandvik AB
Address:	Lerkrogsvägen 19 126 80 Stockholm Sweden
Contacts name:	Agneta Odén, MSc, Ph.D., DDS Director Quality Assurance and Regulatory Affairs
Telephone Number	+46 8 726 66 19
Data Prepared:	January 2001

Device Names:

Comman Name:	Glass reinforced with Aluminium Oxide Particles
Trade Name:	Procera® AllCeram Bridge Material

Predicate Device:
Substantial equivalence is claimed to Nobel Biocare AB´ Procera® AllCeram Fusing Material (K983453).

Device Description:
Procera ®All Ceram Bridge Material is composed of Procera® AllCeram Connection Material (a premixed suspension of aluminium oxide particles, dispersant of the particles, binder for the particles and de-ionized water) and Procera® AllCeram Fusing Material (a suspension of glass material and water). Procera ®All Ceram Bridge Material is used to fuse together sections of core material in densely sintered aluminium oxide of a dental all ceramic bridge.

Intended Use:
Procera Sandvik´s Procera ®All Ceram Bridge Material is intended to be used to fuse together the sections of an aluminium oxide framework for a dental bridge.

Comparison to Predicate:
The following table (Table 7.1 and Table 7.2) provides a comparison of the technological characteristic of the candiate Procera Sandvik´s Procera ®All Ceram Bridge Material to the predicate Nobel Biocare´s Procera ®All Ceram Fusing Material

510(k) Summary (continued)

Table 7.1. Similarities to the predicate

Procera ®All Ceram Bridge Material	Aspect/Characteristic	Comment
	Intended use	Same as predicate
	Fusing temperature	Same as predicate
	Chemical composition of sintered joint glass material	Same as predicate

Table 7.2. Differences from the predicate

Procera ®All Ceram Bridge Material	Aspect/Characteristic	Comment
	Sintered structure of joint material	Candidate is reinforced with aluminium oxide particles. Predicate is not
	Fracture resistance	Candidate has between 24 to 47% increased strength compared to predicate
	Chemical composition of sintered joint material	The glass phase has the same chemical composition as predicate. The candidate contains aluminium oxide particles the predicate does not.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2002

Dr. Agneta Oden
Director, Quality Assurance and Regulatory Affairs
Procera Sandvik AB
Lerkrogsvagen 19, Vastberga
12680 Stockholm,
SWEDEN

Re: K020269
Trade/Device Name: Procera® AllCeram Bridge Material
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 24, 2002
Received: January 28, 2002

Dear Dr. Oden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number (if known): ~~not yet assigned~~ K020269

Device Name: Procera® AllCeram Bridge Material

Indications For Use:
Procera® AllCeram Bridge Material is composed of

Procera® AllCeram Connection Material (a premixed suspension of aluminium oxide particles, dispersant of the particles, binder of the particles and deionised water) and

Procera® AllCeram Fusing Material (a suspension of glass material and water)

Procera® AllCeram Bridge Material is used to fuse together the sections of the core material in densely sintered aluminium oxide of a dental bridge.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020269